The Challenge of Integrating Behavioral and Pharmacological Treatment Beyond Clinical Trial Settings

Presenter: Gary E. Swan, Ph.D., Director, Center for Health Sciences, SRI International (formerly Stanford Research Institute), Menlo Park, California

DHHS Clinical Practice Guidelines recommend the use of behavioral treatments in combination with pharmacological agents as the most effective approach to helping people to quit smoking. Most industry-sponsored randomized clinical trials (RCTs) evaluate the efficacy of medications by including frequent, in-person assessments along with fairly intensive, in-person behavioral counseling. Concern exists, however, that policy decisions based on RCT data have reduced relevance with regard to the use and effectiveness of the therapeutic agents in actual practice. In this setting, there is substantial variability in relevant patient, clinician, treatment, and response characteristics that deviate from the conditions under which the RCTs were conducted and these differences may result in reduced effectiveness of available treatments.

Thus far, behavioral and pharmacological treatments for smoking cessation have been developed independently of each other and are not truly integrated as a smoking cessation *system*. It may, therefore, be unrealistic to expect clinicians to do the integration of the two components at the point of delivery. Some clinicians suggest that concomitant behavioral treatment acts as a barrier to patients who want to quit and advocate the sole use of pharmacologic treatment for smoking cessation or provide a less than optimal level of behavioral assistance.

From an integrated perspective, the behavioral and pharmacological components of a treatment system would act and interact together to determine dynamically the optimal level of combined treatment to best fit the needs of the smoker who wants to quit. A consumer orientation to the development of therapeutic approaches for smoking cessation will necessarily require the integration of biological, psychological, and social priorities that could, in turn, lead to increased acceptance and use of the treatments by consumers, providers, and payers.

A biopsychosocial model of smoking cessation treatment will be presented and includes the following elements: patient characteristics (i.e., demographic, smoking history, psychological, metabolic, receptor density and function, attitudes and beliefs about medication and counseling, and environmental support), clinician characteristics (i.e., economic incentives, time constraints, perceived efficacy, and perceived responsibility), and treatment characteristics (i.e., dose, duration, pharmacokinetic, intensity, content, setting, and convenience) that interact to result in a number of short-term effects (i.e., pharmacodynamics of the drug, abstinence effects, adverse drug effects, and the learning of new skills), patient responses (i.e., adherence to both medication and behavioral regimens, and satisfaction with treatment), smoking outcomes (i.e., continued smoking, nonsmoking, and reduced smoking), health outcomes (i.e., reduced morbidity and mortality), and social/economic outcomes (i.e., increased number of quality-adjusted life years and return on investment). The results of a recently completed effectiveness trial of bupropion conducted in a large health care system will be used to illustrate a number of the components of the proposed model.